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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,969	06/25/2003	Guohua Chen	ARC 3135 R1	6463
23377 7590 06/28/2007 WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891			EXAMINER SILVERMAN, ERIC E	
			ART UNIT 1615	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/606,969

Applicant(s)

CHEN ET AL.

Examiner

Eric E. Silverman, PhD

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2, 7-26, 29-34, 36, 38, 39, 44-56, 59, 60 and 105-121 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 7-26, 29-34, 36, 38, 39, 44-56, 59, 60 and 105-121 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/11/2007 has been entered.

Pursuant to amendment, claims 2, 7 – 26, 29 – 34, 36, 38, 39, 44 – 56, 59, 60, 105 – 121 are pending.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 7 – 26, 29 – 34, 36, 38, 39, 44 – 56, 59, 60, 105 – 121 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendment necessitates several new grounds of rejection under this statute, which are discussed here. The grounds raised in the previous action are discussed below, under the heading "Response to Arguments".

Independent claims 2, 27, and 59 recite an "injectable depot composition", wherein to a polymer is added a solvent "present in an amount sufficient to plasticize

the polymer and form a gel therewith". Applicants' remarks seem to indicate that Applicants' intended the latter to be a requirement that the composition be a gel. However, a gel is highly viscous, and not flowable through a needle. Thus, it is not clear how the composition could be a highly viscous gel and also be injectable. A high viscosity gel would is not injectable, since it cannot flow through a needle.

Claims 10 – 12, 17, 29 – 32, 49, and 59 recite numerical values for polymer molecular weight without reciting the units. Since molecular weight may be measured in different units, such as Daltons, kilodaltons, and atomic mass units, the lack of units renders the claim indefinite. For the purpose of compact prosecution, the Office will interpret these values to be Daltons until the claims are properly amended.

Claims 38 and 39 recite that the polymer comprises a certain amount of the composition. This is unclear. It is possible that applicants intended that the composition comprise a certain amount of the polymer. A clarifying amendment would be helpful.

### ***Response to Arguments***

Applicants' arguments have been fully considered, and are partially persuasive. Applicants' arguments that the term "sufficient to plasticize" is not indefinite is persuasive. Applicants' arguments that the terms "lower alkylene" and "low molecular weight" are defined in the specification are also persuasive.

Applicants' argument that the term "lactic acid-based polymer" is defined is not persuasive. Applicants' aver that the term "lactic acid based" is defined at para. 80, which states in part "a lactic acid-based polymer that can be based solely on lactic acid

Art Unit: 1615

or can be a copolymer based on lactic acid and glycolic acid which may include small amounts of other comonomers ...". This so-called 'definition' is not a definition at all; on the contrary it is merely an example of what the term "lactic-acid based polymer" *can* mean, leaving the artisan to wonder at what else it might mean. Further, the so-called 'definition' is meaningless because it is tautological; defining a "lactic-acid based polymer" as one that is "based ... on lactic acid" provides no information to the artisan, and has no semantic value whatsoever. The specification completely fails to describe what is meant by a polymer "based on" lactic acid, and as such, use of this terminology in the claims renders the claims indefinite.

Claims not specifically discussed above or in a previous action as having indefinite terminology are rejected for depending on one or more of the rejected claims without resolving the issues relating thereto.

#### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1 – 24, 27 – 32, 34 – 47, 49 – 54, 57 – 60 and 105 under 35 U.S.C. 102(e) as being anticipated by WO 02/38185 are **withdrawn** in view of amendment.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1615

Claims 2, 7 – 23, 29 – 34, 36, 38, 39, 44, 45, 47 – 56, 59, 60, 105 – 121 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/238185.

Some of the teachings of the '185 reference have been discussed previously.

The following teachings are also applicable to the newly added claim limitations:

- For delivery in less than seven days, see Example 6, which teaches delivery over three days. Also claim 18 of the reference suggests that the composition may be formulated for administration from about once per three days to once per thirty days. It is understood that a second administration will occur after release of the drug from the first administration is complete. This is a clear suggestion that delivery periods of as little as three days are acceptable.
- For lactic acid-based polymers, and copolymers of lactic acid and glycolic acid see the Examples, which use PLGA.
- For the solvents of claims 107 and 108, 117 and 118, see claim 7, which recites benzyl alcohol. For the solvents of claims 110 and 111 and 120 – 121, claim 7 also recites benzyl benzoate.
- For the weight percent of polymer, see Example 3, which recites 5% by weight, and Example 1, which recites 40% by weight.

The '185 reference does not explicitly require delivery in less than 7 days.

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention select the composition for delivering the agent over less than seven

Art Unit: 1615

days. The reference motivates this in two places. First, delivery over three days is taught to be useful when testing the composition, for example on an animal, as in example 6. Furthermore, claim 18 indicates that delivery times of as little as three days are considered useful and within the scope of '185's teachings.

### ***Response to Arguments***

Applicants' arguments have been fully considered, but are not persuasive.

Applicants' arguments were addressing anticipation rejections, which have been withdrawn. To the extent that those arguments apply to the obviousness rejection above, they are addressed here for the sake of compact prosecution.

Applicant first argues that the WO document teaches flowable compositions, and not gels. Applicant believes that instant claims read only on gels, because the solvent is added to the polymer composition in an amount sufficient "to form a gel therewith". In response, this argument seems to ignore the limitation of instant claims requiring the composition to be "an injectable depot composition". Only flowable compositions are injectable, and thus, instantly claimed composition must be flowable, which is also taught by WO. As such, WO's teaching of "flowable" cannot be said to teach away from instant "injectable" composition. On the contrary, the WO reference teaches or suggests every component of instantly claimed invention, thus rendering the invention obvious in its entirety. Applicants also fail to take into account two significant teachings of the reference. First, on page 7, lines 19 – 30, the WO document teaches that in embodiments where the composition is flowable, it forms a gel after injection. This is the very nature of an "injectable depot composition", which is the type of composition

instantly claimed. Further, in Example 5, the composition solidifies (that is, gels) rapidly after injection, which also meets the requirement of instant claims.

Applicants continue to argue that the WO reference does not suggest the instantly claimed solvent. Applicants reason that the reference exemplifies and prefers NMP, and that the artisan would find a suggestion to use a solvent that is highly miscible in water, and not one with the instantly claimed miscibility. In response, Applicants' arguments fail to take into account that benzyl benzoate is a *claimed embodiment* of the solvent. It cannot be said that a patent application does not suggest the use of an embodiment that is enumerated in the claims. To the extent that such enumeration is not sufficient for an anticipation rejection, the Office does not currently maintain that the claims are anticipated by the '185 reference.

Claims 24 – 26, 46, 55, and 56 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/38185 in view of WO 00/74650 for reasons of record and those discussed below.

### ***Response to Arguments***

Applicants' arguments have been fully considered, but are not persuasive.

Applicants argue that the '650 reference does not overcome alleged flaws in the '185 reference. These supposed deficiencies have been addressed, *supra*.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571




Art Unit: 1615

272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1615

  
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